K011337

OCT 1 6 2001

510(k) Summary

Accumetrics *Ultegra*® System Rapid Platelet Function Assay (RPFA)

Accumetrics, Inc.
3985 Sorrento Valley Blvd.
San Diego, CA 92121

April 30, 2001

For information regarding this 510(k) Summary, please contact Accumetrics, Inc., Rhonda Moe (858) 643-1600.

Device Names:

Trade Name:	Accumetrics *Ultegra* System Analyzer, Accumetrics *Ultegra* System Rapid Platelet Function Assay (RPFA-TRAP) Test Cartridges, Accumetrics *Ultegra* System Level 1 QC *Ultegra* System Level 2 QC
Common Name:	Accumetrics *Ultegra* System Analyzer, Accumetrics *Ultegra* System Rapid Platelet Function Assay (RPFA-TRAP) Test Cartridges, Accumetrics *Ultegra* System Level 1 QC *Ultegra* System Level 2 QC

Classification Name: System, Automated Platelet Aggregation

The Accumetrics *Ultegra* System Analyzer and Rapid Platelet Function Assay have been found to be substantially equivalent to CHRONO-LOG Corporation's Whole Blood Aggregometer (K830749) and CHRONO-PAR Reagent (K760198).

Device Description:
The *Ultegra* System is a turbidimetric based optical detection system which measures platelet induced aggregation as an increase in light transmittance. The system consists of a stand-alone analyzer and disposable test cartridge with reagents based on microbead agglutination technology. The quality control system includes an electronic control and two levels of liquid control. The analyzer controls assay sequencing, establishes the assay temperature, controls the reagent-sample mixing for the required duration, determines the degree of platelet function, displays the results and status information to the user, and performs self-diagnostics. The test cartridge contains a lyophilized preparation of human fibrinogen coated beads, thrombin receptor activating peptide (iso-TRAP), buffer, and preservative. The patient sample is citrated whole blood, which is automatically dispensed from the blood collection tube into the test cartridge by the analyzer, with no blood handling required by the user.

The *Ultegra* RPFA Assay is based upon the ability of activated platelets to bind fibrinogen. Fibrinogen coated microparticles agglutinate in whole blood in proportion to the number of unblocked platelet GP IIb/IIIa receptors. The rate of microbead

agglutination is more rapid and reproducible if platelets are activated. Therefore the reagent iso-TRAP is incorporated into the assay to induce platelet activation without fibrin formation. As activated platelets bind and agglutinate fibrinogen coated beads, there is an increase in light transmittance. The analyzer is designed to measure this change in optical signal due to agglutination.

Intended Use:
The *Ultegra* Rapid Platelet Function Assay (RPFA) is a semi-quantitative, whole blood platelet function assay used to measure glycoprotein (GP) IIb/IIIa receptor blockade in patients treated with abciximab. *Ultegra* RPFA results should be interpreted in conjunction with other clinical and laboratory data available to the clinician.

This indication statement is more specific than the broader statement in the labeling for the CHRONO-LOG Whole Blood Aggregometer: "...measuring platelet aggregation in whole blood or platelet rich plasma." The narrower indication of the *Ultegra* RPFA does not raise issues of safety or effectiveness because the CHRONO-LOG aggregometer is commonly used to measure inhibition of platelet activity in patients treated with abciximab.

Description of Device Modification:
Reagent formulations for the currently marketed RPFA Level 1 and Level 2 QC Controls have been modified to react more closely to the IIb/IIIa binding site of activated platelets. The blue latex reagent in the Level 1 Control has been replaced with a carbon-sol reagent. Human thrombin in the Level 2 Control has been replaced with a GPRPc (glycine-proline-arginine-proline-cysteine) peptide conjugated to an amino dextran. The same level of performance has been maintained with no change to the function, storage conditions or intended use of the product.

Technological Characteristics:
The *Ultegra* Analyzer and the CHRONO-LOG aggregometer utilize optical detection as the measurement method. Both systems are based on measurement of aggregation/agglutination. Both systems are used to determine platelet function.

Certain new characteristics of the *Ultegra* RPFA differ from the CHRONO-LOG. Fibrinogen coated microbeads are used in the *Ultegra* RPFA, but not the CHRONO-LOG aggregometer. The *Ultegra* RPFA uses the agonist iso-TRAP, whereas the CHRONO-LOG uses several different agonists. The *Ultegra* RPFA includes two levels of liquid control, and the CHRONO-LOG does not.

These differences raise no new issues of safety or effectiveness, as shown by the performance characteristics of the two devices.

Performance Characteristics:
The *Ultegra* RPFA performance was compared with the performance of the CHRONO-LOG Platelet Aggregometry in a multi-center clinical trial.

The multi-center clinical trial was designed to study GP IIb/IIIa receptor blockade in patients undergoing percutaneous coronary intervention and receiving abciximab. Samples were obtained at four clinical sites from 120 patients at three time points: 1) Baseline, prior to abciximab administration; 2) During, within 1 hour following post bolus

administration to evaluate the effects of the abciximab bolus; and 2) Post, 24 hours post procedure or at the time of discharge. Samples were tested with the *Ultegra* RPFA and the CHRONO-LOG Platelet Aggregometer.

For the aggregometry method, platelet rich plasma was prepared from the blood sample and tested in the optical model of the aggregometer, using 20 μM ADP as the agonist.

Correlation of the two methods was evaluated using Deming (orthogonal) regression. The results are shown in Table 1.

Regression Method	Deming (orthogonal)
Slope	2.91
Intercept	-48.58
Correlation (r)	0.89

Table 1.

In addition to *Ultegra* RPFA and platelet aggregometry, clinical trial patient samples were tested with a receptor blockade assay (RBA), which measures the percentage of GP IIb/IIIa receptors blocked by abciximab. Figure 1 shows the time course of platelet inhibition for the three methods, as individual points and mean +/- standard error, respectively, and illustrates the overlap in the three assays.

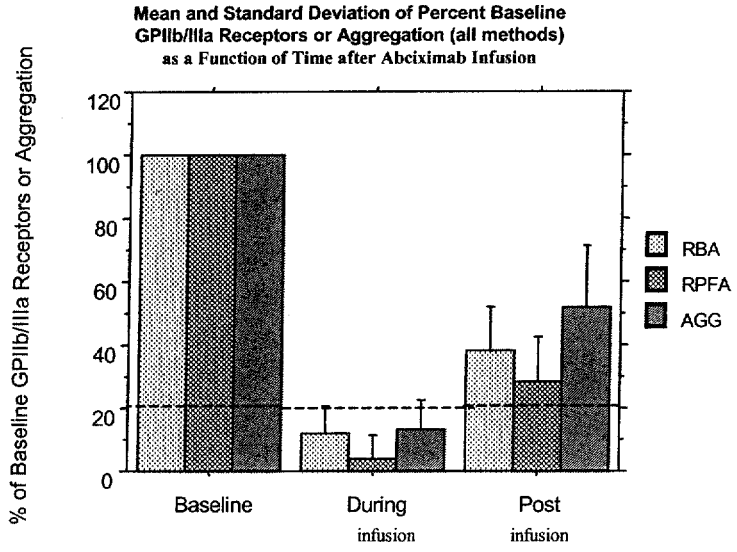

Figure 1.

The results of the multi-center clinical study demonstrate that the performance of the *Ultegra* RPFA is substantially equivalent to that of the predicate device, CHRONO-LOG platelet aggregometer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 6 2001

Ms. Rhonda Moe
Director, Regulatory and Clinical Affairs
Accumetrics , Inc.
3985 Sorrento Valley Blvd
San Diego, CA 92121

Re: k011337
Trade/Device Name: Ultegra® System Rapid Platelet Function Assay (RPFA)
Regulation Number: 21 CFR 864.5700
Regulation Name: Automated platelet aggregation system
Regulatory Class: Class II
Product Code: JOZ
Dated: September 18, 2001
Received: September 20, 2001

Dear Ms. Moe

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011337

Device Name: *Ultegra*® System Rapid Platelet Function Assay (RPFA)

Indications For Use:

The *Ultegra*® Rapid Platelet Function Assay (RPFA) is a semi-quantitative, whole blood platelet function assay used to measure glycoprotein (GP) IIb/IIIa receptor blockade in patients treated with abciximab. *Ultegra* RPFA results should be interpreted in conjunction with other clinical and laboratory data available to the clinician.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K011337

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)